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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action**Application No.**

09/744,866

Applicant(s)

AUSTRUP ET AL.

Examiner

Rawlings L. Stephen

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED _____ FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 10 November 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: 4 and 5.Claim(s) rejected: 1-3, 6, 7, 10 and 22.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☒ Other: See attached Note of Explanation

Note of Explanation

The proposed amendment filed October 3, 2003 fails to place this application in condition for allowance and will not be entered for the following reasons.

The proposed amendment, if entered, would raise the issue of new matter. If the amendment were entered, claims 1, 3, and 10 would recite the limitation, "wherein said tumor cells are not modified by attachment of a particle that comprises an antibody prior to the step of passing the body fluid or part thereof through the screen". Applicant has remarked support for the amended claims can be found in the specification, for example, at page 4, lines 21 through page 5, line 26; at page 6, lines 7-15; and at page 19, lines 16-39. Furthermore, it is noted at page 13, the specification discloses: "Furthermore it is also possible to modify the cancer cells in the cell suspension prior to the screening process, for example by labeling, by attaching particles, by triggering aggregation and/or cluster formation using, for example, suitable antibodies, 30 enzymes, lectins, other ligands and/or receptors or crosslinking reagents, by fixing and by inducing other defined states". These disclosures do not provide the necessary support for the recitation of the limitation in the claims, because the disclosures do not teach the exclusion of a step in which the tumor cells are attached to particles comprising an antibody. The disclosure at page 6 does not address the inclusion or exclusion of a step comprising attaching a particle comprising an antibody to the cells before passing the sample through a screen and thus does not provide the necessary support. While at page 19 the disclosure teaches the cancer cells are successfully provided as isolates from bodily fluids, which are free from the separating agent used, e.g., a particle comprising an antibody, this disclosure does not teach the exclusion of a step comprising attaching a particle comprising an antibody to the cells before passing the sample through a screen. Furthermore, while at pages 5 and 6 the specification teaches some limitations associated with the antigen-specific immunoadsorption-based methods, at page 13 the specification clearly teaches the invention can comprise modifying the cancer cells by attaching particles comprising antibodies prior to the step of screening.

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Accordingly, the proposed amendment would add a limitation to the claims, which appears to be a negative limitation. Adding the expressed exclusion of certain elements implies permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations, in fact, introduce new concepts. See *Ex parte Grasselli*, 231 USPQ 393 (BPAI 1983). Furthermore, Applicant is reminded that it cannot be said that a subgenus is necessarily described by a genus encompassing it and a species upon which it reads. See *In re Smith*, 173 USPQ 679, 683 (CCPA 1972).

Because entry of the amendment would raise new issues, the amendment is not deemed to place this application in better form for appeal by materially reducing or simplifying the issues for appeal.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D., can be reached at (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
January 28, 2004


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600